

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61K 33/06, 33/10, 33/14 A61K 33/20	A1	(11) International Publication Number: WO 86/ 03407 (43) International Publication Date: 19 June 1986 (19.06.86)
(21) International Application Number: PCT/US85/02375 (22) International Filing Date: 3 December 1985 (03.12.85) (31) Priority Application Number: 678,641 (32) Priority Date: 6 December 1984 (06.12.84) (33) Priority Country: US (71) Applicant: RENAL SYSTEMS, INC. [US/US]; 14905 28th Avenue North, Minneapolis, MN 55441 (US). (72) Inventors: COSENTINO, Louis, C. ; 2435 Holly Lane North, Plymouth, MN 55447 (US). HNOJEWYJ, Anatol, M. ; 822 University Avenue, N.E., Minneapolis, MN 55413 (US). JANSEN, Walter, B. ; 4015 Evergreen Lane, Plymouth, MN 55441 (US).	(74) Agent: VIDAS, Scott, Q.; Vidas & Arrett, P.A., 2925 Multifoods Tower, 33 South Sixth Street, Minneapolis, MN 55402 (US). (81) Designated States: AT, AT (European patent), AU, BE (European patent), CH, CH (European patent), DE, DE (European patent), DK, FI, FR (European patent), GB, GB (European patent), IT (European patent), JP, LU, LU (European patent), NL, NL (European patent), NO, SE, SE (European patent). Published <i>With international search report.</i> <i>With amended claims.</i>	
(54) Title: BACTERIOSTATIC HEMODIALYSIS CONCENTRATE		
(57) Abstract <p>Hemodialysis bicarbonate and acid concentrates which are bacteriostatic and bactericidal. Sodium bicarbonate concentrate is made biocidal by including greater than 28 grams per liter of sodium chloride. The excess sodium chloride in the bicarbonate concentrate is obtained from a decrease in the sodium chloride concentration in the acid concentrate. Powdered mixtures having the proper ratios of sodium chloride to bicarbonate may be dissolved in purified water used in hemodialysis to obtain the biocidal hemodialysis concentrates.</p>		

WHAT IS CLAIMED IS:

1. Bacteriostatic animal dialysis concentrate comprising:
sodium bicarbonate and sodium chloride in water, said sodium chloride having a concentration greater than 23.8 grams per liter.
 2. A composition for use in preparing animal dialysis solution from an acid concentrate and a bicarbonate concentrate, said bicarbonate concentrate comprising:
 - a) sodium bicarbonate;
 - b) sodium chloride;
 - c) water; and
 - d) the concentration of said sodium chloride being at least 28 grams per liter of water and no greater than 200 grams per liter.
 3. A composition of matter adapted for use as a hemodialysis bicarbonate concentrate comprising: sodium chloride and sodium bicarbonate, said sodium chloride being in a quantity sufficient such that upon dilution with water said hemodialysis bicarbonate concentrate is bacteriostatic.
 4. A composition comprising sodium chloride and sodium bicarbonate for use in preparing dialysis bicarbonate concentrate solution, said sodium chloride being in a ratio to said sodium bicarbonate such that upon dilution to obtain a bicarbonate concentrate having the desired bicarbonate concentration, said sodium chloride has a concentration greater than 28 grams per liter.
 5. A composition for use in preparing dialysis bicarbonate concentrate, wherein the desired concentration
-



of sodium bicarbonate in the dialysis bicarbonate concentrate is X grams per liter, the composition comprising: sodium bicarbonate and sodium chloride in a ratio of X:Y, Y being the concentration of sodium chloride in the dialysis bicarbonate concentrate and Y being at least 28 and less than about 200.

6. A composition comprising sodium bicarbonate and sodium chloride, expressed in gram ratios as follows:
 $w \text{ NaHCO}_3 : x \text{ NaCl}$ wherein "w" is the desired concentration in grams per liter of sodium bicarbonate in a hemodialysis bicarbonate concentrate prepared from said composition and x is a value of greater than 28.

7. A composition for use in preparing dialysis solution from acid concentrate and a bicarbonate concentrate, said acid concentrate comprising:

- a) sodium chloride;
- b) calcium chloride;
- c) potassium chloride;
- d) magnesium chloride;
- e) acetic acid;
- f) dextrose; and
- g) the concentration of said sodium chloride being less than about 164 grams per liter.

8. A bacteriostatic bicarbonate concentrate composition for use in preparing hemodialysis solution from an acid concentrate and a bicarbonate concentrate, the bacteriostatic bicarbonate concentrate comprising:

- a) sodium chloride;
- b) sodium bicarbonate; and
- c) water, said sodium bicarbonate being at a concentration of between about 50 and about 164 grams per liter, and ~~said sodium chloride being at a concentration~~ of between about 28 and about 200 grams per liter.

9. Combinable aqueous bacteriostatic concentrates for forming upon dilution dialysis solution for using in human dialysis comprising:

a) an acid concentrate including calcium chloride, potassium chloride, magnesium chloride; acetic acid, dextrose and sodium chloride;

b) bicarbonate concentrate including sodium bicarbonate and sodium chloride, said sodium chloride being at a concentration of at least 28 grams per liter, the maximum sodium chloride concentration being about 200 grams per liter.

10. A bacteriostatic bicarbonate concentrate for use in preparing dialysis solution for use in dialyzing animals, said dialysis solution having between about 80 to about 120 milliequivalents each of sodium and chloride derived from sodium bicarbonate, said bicarbonate concentrate comprising:

a) all of the sodium bicarbonate required to yield 15-45 milliequivalents of bicarbonate in the dialysis solution; and

b) sodium chloride in an amount equal to or greater than 28 grams per liter up to all of the sodium and chloride derived from sodium chloride in the dialysis solution.

11. A composition for use in preparing a bacteriostatic bicarbonate concentrate for use in preparing hemodialysis solution, said composition comprising:

a) sodium chloride;

b) sodium bicarbonate; and

c) said sodium chloride being in a quantity such that upon dilution with water to yield a sodium bicarbonate concentration of between about 50 and 164 grams per liter, said sodium chloride concentration will be at least 28 grams per liter and less than about 200 grams per liter.

AMENDED CLAIMS

[received by the International Bureau on 18 March 1986 (18.03.86);
original claims 1, 3, and 4 cancelled; claims 2 and 9 amended; new claim 12 added (3 pages)]

1. (Cancelled)
2. (Amended) In a composition for use in preparing animal dialysis solution from an acid concentrate and a bicarbonate concentrate, said bicarbonate concentrate comprising:
 - a) sodium bicarbonate;
 - b) sodium chloride; and
 - c) water, the improvement comprising: a sodium chloride concentration being at least 28 grams per liter of water and no greater than 200 grams per liter thereby making the concentration bacteriostatic.
3. (Cancelled)
4. (Cancelled)
5. A composition for use in preparing dialysis bicarbonate concentrate, wherein the desired concentration

9. Combinable aqueous bacteriostatic concentrates for forming upon dilution dialysis solution for using in human dialysis comprising:

a) an acid concentrate including calcium chloride, potassium chloride, magnesium chloride; acetic acid, dextrose and sodium chloride;

b) bicarbonate concentrate including sodium bicarbonate and sodium chloride, said sodium chloride being at a concentration of at least 28 grams per liter, the maximum sodium chloride concentration being about 200 grams per liter.

10. A bacteriostatic bicarbonate concentrate for use in preparing dialysis solution for use in dialyzing animals, said dialysis solution having between about 80 to about 120 milliequivalents each of sodium and chloride derived from sodium bicarbonate, said bicarbonate concentrate comprising:

a) all of the sodium bicarbonate required to yield 15-45 milliequivalents of bicarbonate in the dialysis solution; and


b) sodium chloride in an amount equal to or greater than 28 grams per liter up to all of the sodium and chloride derived from sodium chloride in the dialysis solution.

11. A composition for use in preparing a bacteriostatic bicarbonate concentrate for use in preparing hemodialysis solution, said composition comprising:

a) sodium chloride;

b) sodium bicarbonate;

c) said sodium chloride being in a quantity such that upon dilution with water to yield a sodium bicarbonate concentration of between about 50 and 164 grams per liter, said sodium chloride concentration will be at least 28 grams per liter and less than about 200 grams per liter.



12. In a bicarbonate dialysis concentrate comprising water, sodium chloride and sodium bicarbonate, the improvement comprising: a sodium chloride concentration greater than 28 grams per liter and less than the solubility limit of sodium chloride in water, said concentrate thereby being bacteriostatic.